K082725

Section 5
510(k) Summary

FEB 19 2009

Submitter: Siemens Medical Solutions USA, Inc.
Oncology Care Systems
4040 Nelson Avenue
Concord, CA 94520

Contact: Christine Dunbar
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Proprietary Name: PreScision™ Option

Common Name: An accessory to: Accelerator, Linear, Medical

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To:

PRODUCT	Clearance	Claim of Equivalence For:
SIEMENS ARTISTE™	K072485	The Stereo mode with the 160 MLC
SIEMENS ONCOR™ Expression	K060226	ONCOR™ and PRIMUS™ linear accelerator families with Stereo Mode and COHERENCE Workspaces (or the re-branded *syngo®* Suite for Oncology Workspaces) and the 82 leaf MLC marketed as OPTIFOCUS.
SIEMENS PRIMUS™	K993425	PRIMUS™ family of linear accelerators with the Stereo Mode, PRIMEVIEW 3i system, the 58 leaf MLC
Varian Trilogy™	K061140	Steretotactic (SRT) and Stereotactic Radio-Surgery (SRS) Radiation Therapy with high dose beam rate.
TomoTherapy Hi-Art™	K060912	Steretotactic (SRT) and Stereotactic Radio-Surgery (SRS) with unflattened beam delivery and extended treatment field for Stereotactic Body Radiation Therapy.
Accuray Cyberknife™	K052325	Steretotactic (SRT) and Stereotactic Radio-Surgery (SRS) robotic delivery system and increased dose rates for reduced treatment times.

The ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerators with the PreScision™ Option as described in this premarket notification has similar intended use and fundamental scientific technical characteristics as the devices listed above.

Description Summary:

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Within the submission the following internal naming conventions are used:

Market Name	Internal naming convention
ARTISTE™	ARTISTE™ linear accelerator and ACCEL release 4+
ONCOR™ Expression	ONCOR™ linear accelerator and ACCEL release 2+
ONCOR™ Avant-Garde	ONCOR™ linear accelerator and ACCEL release 2+
PRIMUS™	PRIMUS™ linear accelerator and ACCEL release 2+
PRIMEVIEW™	Siemens proprietary verify and record system. The *syngo®* based PRIMEVIEW is hosted on the COHERENCE™ Therapist Workspace. The syngo base version is marketed as PRIMEVIEW3i and is used on the PRIMUS™ linear accelerator systems.
COHERENCE™ Therapist Workspace	RTT Workspace contains the SIEMENS proprietary verify and record system as well as access to the Oncology Information System and directly connects to the LINAC control console.
MVCB	Mega-Voltage Cone Beam – a method of obtaining 3 dimensional data for portal imaging.
160 MLC™	160-leaf multi-leaf collimator
OPTIFOCUS™	82-leaf multi-leaf collimator
OPTIVUE™	aSi flat panel electronic portal imaging device (EPID) AL7 model
OPTIVUE 1000ST	aSi flat panel electronic portal imaging device (EPID) AG9 model
SRT / SRS	Stereotactic Radiation Therapy/ Stereotactic radiosurgery – a method of using high energy, X-Ray photon radiation for precision treatment.
syngo® Therapist Workspace, RTT Express™	RTT Workspace contains the SIEMENS proprietary verify and record system as well as access to the Oncology Information System and directly connects to the LINAC control console on the ARTISTE™ linear accelerator system.
syngo® Suite for Oncology Workspaces	*Syngo* based workstation, re-branded COHERENCE workspaces.
syngo®	Siemens proprietary software architecture and hosting SIEMENS software applications organized by task cards on a dedicated workstation.

For further definitions of the terms used in this submission, refer to the Glossary in Section 24.

Technological Characteristics:

The PreScision™ Option:

The PreScision™ Option package is an optional feature to the existing SIEMENS ARTISTE™, ONCOR™ and PRIMUS™ family of medical linear accelerator devices [LINAC]. The basic design, safety features and function of the LINAC remain unchanged. The PreScision feature supports Stereotactic Radiation Therapy (SRT) and Stereotactic Radio-surgery (SRT) using the conventional linear accelerator and subsystems for the delivery of precision high dose X-Ray photon energy for treatment of lesions, tumors and conditions anywhere in the body where radiation therapy is indicated.

The PreScision option supports the delivery of up to 2,000 (± 2%) MU / Minute X-Ray photon beam for either single-session radiosurgery or hypo-fractionated stereotactic treatment using a calibrated 6.67 MV photon energy spectrum consisting of an unflattened beam geometry, a selectable field size

of 5cm x 5 cm up to 40cm x 40 cm, collimated by any validated third party stereotactic accessory such as a stereotactic cone or a Multi-leaf collimator, with or without the use of patient motion detection or physiologic gating.

The control console will support the PreScision feature with one unflattened beam energy labeled as "7UF" to differentiate from the previous 6 MV unflattened beam energy used by the predicate Stereo feature. The 7UF option replaces the existing "Stereo" option previously cleared under the PRIMUS™ (K993425) and ONCOR™ (K031764, K060226) and ARTISTE (K072585) devices.

The unflattened X-Ray photon energy spectrum is similar to the 6 MV energy spectrum as used by the PRIMUS™, ONCOR™, ARTISTE Linear Accelerator systems for the predicate Stereo option and is similar to the energy spectrum of the TomoTherapy Hi-Art system as described in Section 11, Design Description.

The SIEMENS linear accelerator product requirements for the PreScision™ option consists of the following:

A SIEMENS ARTISTE™, ONCOR™ or PRIMUS™ Family of Linear Accelerators with the minimum configuration of:

- COHERENCE™ Therapist Workspace or the *syngo®* Radiation Therapist (RTT) with embedded PRIMEVIEW™ Record and Verify system or the RT Express™ system for the ONCOR™or ARTISTE™ linear accelerator systems.
- PRIMEVEIW 3i Record and Verify system used with the PRIMUS™ linear accelerator system.
- 58 leaf multi-leaf collimator (MLC) marketed as 3D-MLC, 82 leaf MLC marketed as OPTIFOCUS™ or the 160 Leaf MLC for:
    - Stereotactic Radiotherapy
    - Stereotactic Radiosurgery
    - Fixed fields,
    - Auto-sequenced,
    - Arc (Rotation) and
    - Intensity Modulated Radiation Therapy (IMRT) treatment delivery methods,
- MLC interface to support the SIEMENS ModuLeaf MLC (K030609) for precision Stereotactic or Stereotactic Radiosurgery Radiation TherapyTreatments.
- Gating interface to support Third party, cleared, gating devices for physiologic or patient motion detection.
- Stereotactic mode to support Third party, cleared, stereotactic hardware and patient fixation positioning devices.
- An amorphous Silicon (aSi) flat panel electronic portal imaging device (EPID) marketed as OPTIVUE 1000ST
- patient treatment couch; 550 TxT™ (K050422), or the ZXT™ (K910971).

Refer to Section 11 Design Description, for the Product Specification regarding these specific product features.

General Safety and Effectiveness:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software development, verification of

requirements and validation testing. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards.

Intended Use:

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

The LINAC is a high-dose and high-dose rate medical linear accelerator optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT) and when used in conjunction with the PreScision™ option, supports precision stereotactic applications. The stereotactic applications include single-session radiosurgery, fractionated stereotactic radiation therapy, fractionated stereotactic intensity modulated radiation therapy for lesions, tumors and conditions anywhere in the body where radiation therapy is indicated.

The *syngo®* Suite for Oncology Workspaces:

The *syngo®* workspaces includes a number of *syngo®* based software applications whose indication for use include the viewing, processing, filming, and archiving of medical images. The workspaces also permit patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording.

Summary:

In summary, it is SIEMENS' belief that the addition of the PreScision option for enhanced stereotactic radiation therapy and stereotactic radiosurgery (SRT / SRS) does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2009

Ms. Christine Dunbar
Senior Regulatory Affairs Specialist
Siemens Medical Solutions, USA, Inc.
Oncology Care Systems
4040 Nelson Avenue
CONCORD CA 94520

Re: K082775
Trade/Device Name: PreScision™ Option
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 19, 2008
Received: September 22, 2008

Dear Ms. Dunbar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4

Indication For Use Statement

510(k) Number (if known): K082775

Device Name: PreScision™ Option

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082775

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109)